K103467

JUN 2 8 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245

Contact: Shiven Gandhi
Regulatory Affairs Associate
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Date Prepared: 14th June 2012

Device Identification:
Common Name: Video Rhino-Laryngoscope System

Trade Name: CMOS Video Rhino-Laryngoscope System

Predicate Device: KARL STORZ VIDEO RHINO-LARYNGSCOPE SYSTEM, MODEL11101SERIES (K072387)

Indication: The KARL STORZ CMOS Flexible Video Rhino-Laryngoscope System may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique. The endoscope is used for endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor.

Device Description:
The Karl Storz CMOS Video Rhino-Laryngoscope System includes a flexible endoscope and a monitor. The rhino-laryngoscope consists of an integrated light located in the handle. The light is transmitted thought the fiber optic bundles and illuminates the anatomy under visualization. A new Storz specific CMOS imaging sensor located at the distal tip of the endoscope shaft which is inserted into the body cavities. The captured video signal is then transferred to the C-MAC monitor for display purposes. The Karl Storz CMOS Video Rhino-laryngoscope is a Class II device under 21 CFR874.4760, Rhino-Laryngoscope and accessories.

Substantial Equivalence:
The Karl Storz CMOS Video Rhino-Laryngoscope System is substantially equivalent to the predicate device (K072387) since the intended uses and the technological characteristics are the same. The minor differences between the Karl Storz CMOS Video Rhino-Laryngoscope System and predicate device raise no issue of safety and effectiveness, as these differences have no effect on the performance, function or general intended use of these devices.

Technological Characteristics Comparison Table

	Subject Device	Predicate Device (K072387)
Applicant	Karl Storz Endoscopy America, Inc.	Karl Storz Endoscopy America, Inc.
Device Name	Karl Storz CMOS Video Rhino-Laryngoscope	Karl Storz Video Rhino-Laryngoscope
Type of Device	Videoscope System	Videoscope System
Indication for use	For endoscopic diagnosis within the nasal lumens and airway anatomy.	For endoscopic diagnosis within the nasal lumens and airway anatomy.
Imaging Sensor	CMOS	CCD
Illumination source	LED	Xenon
Working Length	Same	Same
Shaft Diameter	Same	Same
Data Storage	Yes	Yes

Non-Clinical Performance Data:
The Karl Storz Flexible Video Rhino-Laryngoscope system has been successfully tested for its functions, performance and safety as per FDA recognized standards. Testing has been conducted as per IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, and ISO 10993 to address the safety aspect of the device. The performance of the device is tested by complying with ISO 8600.

Reprocessing:
The CMOS Video Rhino-Laryngoscope is cleaned using manual cleaning with enzymatic detergent and is subjected to high level disinfection using CIDEX OPA. No methods of sterilization are validated for the CMOS Video Rhino-Laryngoscope. The cleaning and high-level disinfection studies were perform in accordance with AAMI TIR 12:2010 (Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers), AAMI TIR 30:2003 (A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices), AAMI 7: 1999 (Chemical Sterilants and High-Level Sterilants: A Guide to Selection and Use), AAMI E 1837 (Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices) and FDA draft guidance for Processing/Reprocessing Medical devices in Healthcare settings (dated: May 2,2011)

Conclusion:
Hence the CMOS Video Rhino-Laryngoscope system is as safe and as effective to the predicate device in terms of its intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 28 2012

Karl Storz Endoscopy America Inc.
c/o Mr. Shiven Gandhi, Regulatory Affairs Associate
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K103467
Trade/Device Name: Karl Storz CMOS Video Rhino Laryngoscope System
Regulation Number: 21 CFR 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: June 14, 2012
Received: June 15, 2012

Dear Mr. Gandhi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K103467

Indication for Use

510(k) Number (if known):

Device Name: Karl Storz CMOS Video Rhino-Laryngoscope System

Indication for use: The KARL STORZ CMOS Flexible Video Rhino-Laryngoscope System may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique. The endoscope is used for endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel C Clapper

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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